The SEP361-203 study is divided into 3 main parts.

Screening/washout period (up to 2 weeks)

You will visit the study center (Visit 1) to learn about the study and so that the study doctor can check whether the study is right for you. If you are eligible and decide you would like to join the study, you may need to visit the study center on more than 1 day to have all screening assessments performed.

During this period you may need to stop taking some of your current medications; your study doctor will discuss this with you.

Treatment period (approximately 8 weeks)

During this period you will take 1 capsule of the study medication (investigational medication or placebo) per day at approximately the same time each evening at bedtime.

You will visit the study center up to 6 times and receive up to 7 telephone calls during this period for tests and assessments and to check your health while receiving the study medication.

During the first 2 weeks you will meet every day with your caregiver (outside of the study center) to take part in a social interaction program, which will be designed around your interests and capabilities.

Follow-up period (approximately 1 week)

You will visit the study center once for a follow-up visit for final safety assessments about 7 days after taking the last dose of study medication.

Who should I contact for more information?

The study team can give you more information about the SEP361-203 study and answer any questions you might have. Please remember that taking part in this research study is voluntary.

To find out more about the SEP361-203 study and to view study center locations, visit www.pdpclinicaltrial.com.

Thank you for your interest in the SEP361-203 study.

Patient Brochure, 12 Sept 2018 [V02 USA]

SEP361-203 Study

Patient Information

Learn about a research study evaluating an investigational medication in people with Parkinson's disease with symptoms of psychosis

Thank you for your interest in the SEP361-203 study!

Doctors are conducting a clinical research study to evaluate an investigational medication in people diagnosed with Parkinson's disease who have experienced symptoms of psychosis. The study results will provide information about the safety of the investigational medication and how well it works. Patients who choose to take part in clinical research studies provide a valuable contribution to medical research.

What is Parkinson's disease psychosis?

Parkinson's disease is a neurodegenerative condition. This means that if you have Parkinson's disease, your brain will change over time causing problems like losing control of how your body moves. You may also experience other symptoms such as visual hallucinations (seeing things that aren't actually there), delusions (such as paranoia), or illusions (thinking something is real when it is not). You may hear these symptoms referred to as 'Parkinson's disease psychosis', which is common in people with Parkinson's disease.

What is the SEP361-203 study?

The SEP361-203 study is a clinical research study in people with Parkinson's disease with symptoms of psychosis. This study will evaluate how safe the investigational medication is and how well it works.

The SEP361-203 study is looking for adult participants who:

- are male or postmenopausal female 55 years of age or older
- have been diagnosed with Parkinson's disease for at least 1 year
- have experienced symptoms such as visual hallucinations, delusions, and/or illusions
- have a caregiver (e.g. spouse or family member) who will be able to attend all study visits with them.

Approximately 36 patients across approximately 12 clinical research sites in the US will take part in the study.

All study-related visits, tests, and study medication will be provided at no cost for the duration of the study. In addition, reimbursement for travel and related expenses may be provided for completed study visits.

Deciding to take part in a clinical research study is an important decision. If you have any questions, please contact the study team using the details on the back of this brochure.

What will happen during the SEP361-203 study?

Before you begin the study, you will be screened to determine your eligibility. If you are found to be eligible and agree to participate, you will be randomly placed into 1 of 2 study groups. One group will receive the investigational medication and the other group will receive placebo (which looks the same as the investigational medication but contains no active medication). There is a 2-in-3 chance that you will receive the investigational medication.

The study will last for approximately 11 weeks and involve up to 8 visits to the study center, as well as phone calls in between visits. At each of the visits to the study center you will undergo assessments and tests so that the study team can closely monitor your physical and mental health. These assessments and tests will be clearly explained to you by the study doctor. Your caregiver will need to be in daily contact with you and come with you to all visits at the study center.

The study medication is an oral capsule that you will take once daily at bedtime throughout the treatment period (8 weeks). During your time in the study you will continue to take your current anti-Parkinson's disease medications on a stable dose; however, before receiving any study medication you may be asked to stop taking some of your other medications (your study doctor will discuss this with you).